**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

**REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW**

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Page(s)**

**Cases**

**Statutes**



**Other Authorities**

Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC (collectively, "Quincy" or "Defendants") respectfully submit this reply brief in further support of their motion pursuant to Federal Rule of Civil Procedure 50(b) for entry of judgment as a matter of law in their favor on all counts (Dkt. 450) ("Motion" or "Mot.").

## I. PRELIMINARY STATEMENT

Defendants' opening brief established that they are entitled to judgment as a matter of law on all eight of the alleged marketing claims for Prevagen® being challenged at trial (the "Challenged Claims") because the NYAG[1] failed to prove that any Prevagen advertisement would mislead any consumer. The NYAG's Opposition to Defendants' motion ("Opp.") contains numerous leaps of logic and inferences that are not supported by the trial record or the law, and confirms Defendants' entitlement to judgment as a matter of law.

The NYAG wilted in the face of Defendants' challenge to identify the two Challenged Claims that the jury found the NYAG satisfied its burden of proof on under New York's General Business Law (the "Jury Verdict Claims") in any advertisement in evidence. That is because the Jury Verdict Claims were never disseminated and the NYAG failed to introduce any evidence suggesting otherwise, including any extrinsic evidence.

Moreover, Defendants are entitled to judgment as a matter of law on all Challenged Claims because the NYAG did not and cannot point to any evidence suggesting that any of its expert

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[1] It remains unclear why the Federal Trade Commission ("FTC") is joining in the NYAG's opposition to Quincy's motion. Despite the fact that FTC attorneys were permitted to question witnesses at the trial, there can be no dispute that only the NYAG's claims were presented to and decided by the jury.

witnesses viewed or were aware of any advertisement containing the Challenged Claims. And therefore they could not (and did not) opine that any of the challenged advertisements were misleading or unsubstantiated. Of course, understanding what message an advertisement conveys is the logical and necessary first step in offering an opinion as to whether or not an advertisement is adequately substantiated. But the NYAG's Opposition confirms its experts did neither.

In addition, the NYAG cites nothing in the trial record to rebut Dr. Kurzer's statements that the addition of vitamin D also supports the Challenged Claims.

Finally, with respect to the NYAG's Executive Law claim, the NYAG merely rehashes already rejected arguments and ignores that it is the law of the case that there is no independent cause of action under that statute, and that liability under the Executive Law cannot stand in light of the jury's findings on the GBL claims.

For all of these reasons and as set forth in Quincy's opening brief and summary judgment briefing, Defendants are entitled to judgment as a matter of law in their favor on all counts.

## II. ARGUMENT

### A. The NYAG's Opposition Confirms That The Jury Verdict Claims Were Not Conveyed In Any Prevagen Advertisement Presented At Trial.

Defendants are entitled to judgment as a matter of law in their favor because the Jury Verdict Claims *were not made* in any advertising introduced into evidence at trial. As set forth in Quincy's opening brief, the two Jury Verdict Claims—"Prevagen reduces memory problems associated with aging" and "Prevagen is clinically shown to reduce memory problems associated with aging"—are not found in any piece of evidence submitted to the jury. (Mot. at 4–7.)

In its opening brief, Defendants challenged the NYAG to point out the specific pieces of evidence in which the Jury Verdict Claims were expressly made. (*Id.* at 4–5.) The NYAG was unable to do so (despite characterizing this simple request as "shocking" or "desperate.") (Opp.

at 2.) The only shocking aspect of Defendants' challenge is that the NYAG cites only five trial exhibits and limited language from each—***none of which expressly matches the language of the Jury Verdict Claims***. (*Id.* at 2–3 (citing JX-81, JX-84, JX-89, PX-584, PX-587).) Rather, the NYAG just *argues*—based on nothing more than its own say-so—that the Jury Verdict Claims were conveyed in these exhibits.

For example, the NYAG cites the following statements from three commercials as *expressly* conveying the Jury Verdict Claims: (JX-81 ("I oversee approximately 20 people and my memory just has to be sharp. I always hear people say, you know, when you get older people lose memory. I didn't want to be that person. I decided to give Prevagen a try. My memory became much sharper. I remembered more."); JX-84 ("As I was writing I found that I just wasn't as sharp and I knew I needed to do something. So I started taking Prevagen. I realized that I was much more clear and I was remembering the details I was supposed to."); JX-89 ("I started noticing my memory was slipping. I saw a Prevagen commercial and I did some research on it. I started Prevagen about 3 years ago. I feel clearer in my thoughts. My memory has improved. And generally just more on point.").) None of these commercials state that "Prevagen reduces memory problems associated with aging" or that "Prevagen is clinically shown to reduce memory problems associated with aging." Therefore, the Jury Verdict Claims are not express claims.

Nor do the Prevagen labels cited by the NYAG expressly convey the Jury Verdict Claims. Instead, these labels say that Prevagen can "help" with "mild" memory problems or "mild" memory loss associated with aging, (*see* PX-587 at Ex. D pp. 3, 5, 6; *id.* at Ex. E pp. 2, 5, 8, 9, 11, 12), that Prevagen can "protect memories" in "minds over 40," (*see id.* at Ex. C p. 2), and that Prevagen Professional "is for" memory problems associated with aging (*see id.* at Ex C p. 4.)

Given that none of Prevagen's marketing materials expressly made the Jury Verdict Claims, the NYAG failed to satisfy its burden of proof and Defendants are entitled to judgment as a matter of law.

If the NYAG intended to proceed under an "implied claim" theory, it was required to present extrinsic evidence of how reasonable consumers interpreted the at-issue advertising. But the NYAG did not pursue such a theory at trial, failed to present evidence of how any consumers interpreted the challenged advertisements, and instead continues to argue that it was not required to do so. (Opp. at 4–7.) The NYAG's arguments are unavailing.

First, the NYAG overstates the Court's prior orders with respect to consumer perception evidence. In its motion *in limine* ruling, the Court merely held that Defendants could not argue *to the jury* that evidence of consumer perception "is required." (Dkt. 379, at 1.) That Order says nothing about whether such evidence is legally required in order to establish an implied marketing claim. Nor did the Court's summary judgment order address this legal requirement; it simply held that the apparent battle of experts precluded summary judgement. (Dkt. 331, at 16.) Indeed, the Court's ruling that "evidence of consumer perception is superfluous if [it is proven] at trial that defendants did not possess the necessary scientific substantiation to support the challenged statements," (*id.* at 6), begs the question of what the challenged statements are in the first place. Before even reaching substantiation, the NYAG was first required to establish what claims were conveyed in Prevagen's marketing. And since the Jury Verdict Claims were not expressly made in any Prevagen label or advertisement, the NYAG was required to present consumer perception evidence in order to meet its burden on this first step. It failed to do so.

Second, the NYAG has not meaningfully distinguished Defendants' *New York* caselaw—including some cases addressing GBL claims—requiring extrinsic evidence to establish implied

marketing claims. (Mot. at 5–7); *see, e.g.*, *Colangelo v. Champion Petfoods USA, Inc.*, No. 6:18-cv-01228, 2022 WL 991518, at *21 (N.D.N.Y. Mar 31, 2022), *aff'd sub nom Paradowski v. Champion Petfoods USA, Inc.*, No. 22-962, 2023 WL 3829559 (2d Cir. June 6, 2023); *de Lacour v. Colgate-Palmolive Co.*, No. 1:16-cv-08364, 2024 WL 36820, at *7 (S.D.N.Y. Jan. 3, 2024); *In re KIND LLC "Healthy and All Natural" Litig.*, 627 F. Supp. 3d 269, 282 (S.D.N.Y. 2022); *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 6346 F. Supp. 2d 510, 525 (S.D.N.Y. 2009). The NYAG simply argues—with no legal support—that the marketing claims at issue in those cases were "vague" or "context-dependent statements susceptible to different meanings." (Opp. at 6.) This is plainly insufficient to relieve the NYAG of its evidentiary burden. The NYAG also ignores that (1) *Colangelo, de Lacour* and *In re KIND* were all decided under the GBL—the same statute at issue in this case; and (2) while *Stokely* was decided under the Lanham Act, New York courts have ruled that the GBL standards are the same as those applied under the Lanham Act. *See Naked Cowboy v. CVS*, 844 F. Supp. 2d 510, 518 (S.D.N.Y. 2012).

Tellingly, the NYAG does not cite any GBL case (or any New York case at all for that matter) to support its argument that it did not have the burden to introduce extrinsic evidence. Nor does it cite any New York law for its proposition that a claim can be "clearly and conspicuously implied" without the need to establish the claim through extrinsic evidence. (Opp. at 5.) Instead, the NYAG once again resorts to inapplicable, procedurally inapposite, and out-of-Circuit cases discussing the FTC Act. (*Id.*) But even these FTC cases acknowledge that consumer perception evidence may be required for implied claims. *See FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008) ("This question of fact [whether a representation was made] may be resolved by the terms of the advertisement itself *or by evidence of what consumers interpreted the advertisement to convey*") (emphasis added); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957–58

(N.D. Ill. 2006) (acknowledging difference between express and implied claims and that in some instances, under the FTC Act, extrinsic evidence is required). These cases do nothing to alter the NYAG's burden to submit consumer perception evidence to establish that any implied claims, such as the Jury Verdict Claims, were made and what message they conveyed to consumers.

Now, perhaps realizing its failure of proof, the NYAG relies on Todd Olson's affirmative answer to a question about whether the "Grandparents" commercial (PX-584) "suggests to consumers that Prevagen ***can help them with mild memory problems associated with aging.***" (Opp. at 3 (emphasis added).) Perhaps the NYAG inadvertently asked the wrong question, but the question posed to Mr. Olson does not ask whether the commercial conveys the Jury Verdict Claims—*i.e.*, whether Prevagen "reduces memory problems associated with aging." Rather, the NYAG asked Mr. Olson whether the Grandparents commercial suggested that Prevagen "can help" consumers with "mild" memory problems associated with aging. (*Id.*) Thus, Mr. Olson's testimony does nothing to buttress the NYAG's position, because neither the question nor the answer track the language of the Jury Verdict Claims.

But even if Mr. Olson's testimony did track the language of the Jury Verdict Claims, such testimony would *still* be insufficient to support the NYAG's position about what claims were conveyed in Prevagen's advertising. Defendants' Motion set out caselaw that an employee's testimony is "insufficient to establish a reasonable consumer's understanding" of challenged advertising, and instead just represents "the view of [that] individual." *de Lacour*, 2024 WL 36820, at *4, 7 (cited at Mot. at 6). The NYAG fails to address, much less distinguish, this case law. That is because it cannot.

Finally, the NYAG once again seeks to flip the burden of proof in this matter on its head by asserting that "Defendants do not suggest an alternative meaning or interpretation that

consumers have understood their claims about Prevagen to mean." (Opp. at 7.) Putting aside the obvious alternative meaning associated with any product formulated to improve memory, (*i.e.*, take the product and you should realize a memory benefit over time), Defendants have no obligation to establish that an alternative meaning exists. It is undisputed that *the NYAG* bore the burden at trial to establish each and every one of the Challenged Claims were made. *People v. Gen. Elec. Co.*, 302 A.D.2d, 314, 315 (1st Dep't 2003) ("[T]he plaintiff must prove the challenged act or practice was misleading in a material way and the deceptive practice must be likely to mislead a reasonable consumer acting reasonably under the circumstances." (citation omitted)). It did not even try to satisfy this burden with respect to the Jury Verdict Claims. This "complete absence of evidence" warrants granting Defendants' judgment as a matter of law. *See Conte v. Emmons*, 895 F.3d 168, 171 (2d Cir. 2018) (citation omitted).

**B. The NYAG Failed To Satisfy Its Burden That Any Challenged Claim Was Unsubstantiated Or Deceptive.**

**1. The NYAG's Opposition Does Not Dispute The NYAG Failed To Offer Any Witnesses Who Viewed Or Opined On Any Challenged Claim In Prevagen Advertising**

Defendants' Motion established that they are entitled to judgment as a matter of law on all claims because the NYAG presented no evidence whatsoever that the Challenged Claims would mislead a consumer. (*See* Mot. at 7–11); *Gen Elec. Co.*, 302 A.D.2d at 315 ("[T]he plaintiff must prove that the challenged act or practice was misleading in a material way and the deceptive practice must be likely to mislead a reasonable consumer acting reasonably under the circumstances" (internal citations omitted)).

The NYAG characterizes evidence that a consumer would be misled as "certain types of proof that are not required and not relevant." (Opp. at 7.) But it goes without saying that "[t]he primary evidence in a consumer-fraud case arising out of allegedly false advertising is, of course,

the advertising itself." *Miller v. Sanofi Consumer Healthcare*, No. 1:22-cv-00574, 2023 WL 112553, at *2 (S.D.N.Y. Jan. 5, 2023) (Stanton, J.) (citing *Fink v. Time Warner Cable*, 714 F.3d 739, 742 (2d Cir. 2013)); *see also Brumfield v. Trader Joe's Co.*, No. 1:17-cv-03239, 2018 WL 4168956, at *2 (S.D.N.Y. Aug. 30, 2018); *Cosgrove v. Oregon Chai, Inc.*, 520 F. Supp. 3d 562, 576 (S.D.N.Y. 2021). Thus, far from being "not required and not relevant" in an allegedly false advertising case, whether an advertisement is misleading is *the most relevant* proof requirement for a plaintiff. *Id.*

Here, the NYAG not only failed to present any evidence whatsoever that any of the Challenged Claims made in Prevagen's advertising would mislead a consumer, *none* of the NYAG's experts (its only witnesses) were familiar with, or could even identify, the Challenged Claims from Prevagen's advertising. And because they did not review the advertising itself, they could not have opined that the advertising was false, misleading or unsubstantiated. (*See* Mot. at 11–15; *see also* Trial Tr. at 300:7–18 (Dr. Sano admitting she did not review any Prevagen advertisement, that she did not know what marketing claims the NYAG was challenging in this action, and that she was not offering any opinion on Prevagen marketing); *id.* at 483:21–24, 494:13–14 (Dr. Wittes confirming she did not know what any of the Challenged Claims were, did not review any advertising and did not know anything about the relationship between the science and advertising claims).)

As the Court previously told the NYAG, the "question for trial is whether defendants had the necessary scientific evidence to support the claims defendants ***made while advertising*** Prevagen . . . [i]ts determination ***depends on the match between defendants' statements and the proof***." (Dkt. 331, at 15 (emphasis added).) Accordingly, in order for the NYAG's expert witnesses to attempt to "match" the statements and the proof, they first needed to know what the

advertising statements were. The NYAG's Opposition acknowledges that this first step is necessary, (*see, e.g.*, Opp. at 7 (stating, without any supporting citation, that "Plaintiffs' experts presented testimony regarding the lack of substantiation that Defendants has ***for those advertising claims***" (emphasis added)); *id.* at 8 (stating, without any supporting citation, the "Plaintiffs met this burden by establishing that Quincy lacked competent and scientific evidence ***to support the claims***" (emphasis added)), but the NYAG then flip-flops on this point by asserting that "[t]here was no need for any fact or expert witness to review the advertising at issue on behalf of Plaintiffs to determine that the proffered substantiation did not comprise competent and reliable scientific evidence," (*id.* at 9.) That argument strains credulity.

It is axiomatic that in order for an expert to determine whether an advertisement is materially misleading, the first necessary step is to view the advertisement. *See Miller*, 2023 WL 112553, at *2. Without doing so, an expert's opinion is made in a vacuum and worthless. *See Shatkin v. McDonnell Douglas Corp.*, 565 F. Supp. 93, 95 (S.D.N.Y. 1983) ("An expert's opinion that is founded in conjecture that is inconsistent with the record has no evidentiary value."); *see also Boots v. Stanley Black & Decker, Inc.*, 132 F. Supp. 3d 307, 317 (N.D.N.Y. 2015) ("An expert's opinions that are without factual basis and are based on speculation or conjecture are simply inappropriate." (internal citation omitted)); *Macaluso v. Herman Miller, Inc.*, No. 7:01-cv-11496, 2005 WL 563169, at *8 (S.D.N.Y. Mar. 10, 2005) ("An expert's opinion based on incorrect factual assumptions renders all of his subsequent conclusions purely speculative."). Here, the NYAG's experts admitted they did not view any—and were not aware of any—of the challenged advertising or the Challenged Claims, and therefore their opinions are completely irrelevant.

Moreover, as the Court properly instructed the jury:

> The presence of disclaimers may affect the above considerations, including what claims were actually conveyed ***and whether the claim was materially misleading***, and you should keep this in mind when answering the verdict form. You should consider whether a disclaimer or a qualifier is sufficiently clear and conspicuous, that when the full marketing claim is considered, the claim actually conveyed, is not the one that the Attorney General alleged was made and eliminates the possibility that a reasonable consumer would be mislead.
>
> In evaluating the efficacy of such a disclaimer, you can consider such factors as wording, font size, placement, and emphasis of the disclaimer.

(Trial Tr. at 1447:2–13 (emphasis added).) Each of the videos and labels cited by the NYAG contain disclaimers and qualifying language. Because the NYAG's experts did not review the challenged advertising material, they were not aware of these disclaimers and qualifiers, and their opinions were necessarily limited to the language of the Challenged Claims as provided to them by the NYAG's counsel.

For example, every single label and commercial cited in the NYAG's brief (indeed, every piece of marketing admitted into evidence at trial) contains the express disclaimer that the Challenged Claims (including the advertising that the NYAG claims includes the alleged Jury Verdict Claims) "have not been evaluated by the Food and Drug Administration" and that Prevagen "is not intended to diagnose, treat, cure or prevent any disease." (*See* JX-81, JX-84, JX-89, PX-584, PX-587.) Many of the labels the NYAG cites further qualify that the Madison Memory Study showed improvement in "certain" aspects of cognitive function. (*See* PX-587 at Ex. E pp. 5–12.) Still other advertisements contain additional disclaimers. (*See* Dkt. 453, at 15.) But the NYAG failed to share these disclaimers with their experts and therefore those experts could not have opined on whether the advertisements were misleading or adequately substantiated.

Defendants, therefore, are entitled to judgment as a matter of law because the NYAG's experts could not have offered relevant opinions on the substantiation of advertisements and disclaimers that they never even saw. *See, e.g.*, *Karibian v. Columbia Univ.*, 930 F. Supp. 134, 150 (S.D.N.Y. 1996) (granting motion for judgment as a matter of law "because there was no reasonable basis in the evidence to support the jury's verdict.").

**2. The NYAG's Opposition Confirms That None Of Its Expert Witnesses Applied The Competent And Reliable Scientific Evidence Standard.**

Defendants are also entitled to judgment as a matter of law with respect to all Challenged Claims because the NYAG's experts did not view the "proof" under the applicable competent and reliable scientific evidence standard for dietary supplements. (*See* Dkt. Mot. at 11–14; Opp. at 10–11 (admitting that "*Defendants'* experts offered their opinions at trial as to whether or not the claims at issue in this case were supported by competent and reliable scientific evidence" (emphasis added)).) To be clear, Defendants are *not* claiming that the NYAG's experts should have "opine[d] on the proper legal standard or attempt[ed] to explain the law." (Opp. at 14.) But, in order for their expert opinions to be relevant, the experts should have been made aware of the applicable standard before forming their opinions.

Throughout this litigation, the NYAG has taken the absurd position that its experts do not need to know what competent and reliable scientific evidence means, going so far as to say the definition is "irrelevant." (*Id.*) As the Court made clear at the outset of trial, such a position "is simply unreasonable." (Trial Tr. at 7:11–20.) And this Court has stated, time and again, "whether defendants had the necessary scientific evidence to support the claims defendants made while advertising Prevagen" is the key issue in this case. (Dkt. 331, at 15.) This "determination depends on the match between the defendants' statements and the proof," (*id.*), and their ignorance of the

competent and reliable scientific evidence standard precluded them from analyzing the "proof" under the appropriate scientific and legal framework.

Courts have routinely held that awareness and consideration of the competent and reliable scientific evidence standard is required to understand the degree of scientific substantiation evidence typically required in the dietary supplement industry and to ensure that experts' opinions are relevant to and consistent with that applicable standard. *See United States v. Bayer Corp.*, No. 2:07-cv-00001, 2015 WL 5822595, at *3, 14 (D.N.J. Sept. 4, 2015) ("[C]ompetent and reliable scientific evidence does not require drug-level clinical trials, and the Government cannot try to reinvent this standard through expert testimony."); *see also Basic Rsch., LLC v. FTC*, No. 2:09-cv-00779, 2014 WL 12596497, at *13 (D. Utah Nov. 25, 2014) (granting summary judgment because the FTC's expert "failed to apply the proper standard" and required "a level of substantiation that exceeds" the competent and reliable scientific evidence standard); *FTC v. Garden of Life, Inc.*, 516 F. App'x 852, 854 (11th Cir. 2013) (rejecting the FTC and its expert's attempt to read additional requirements into the competent and reliable scientific standard).

Yet, the NYAG's witnesses were completely unaware of the standard that Quincy's substantiation must be held to.

The NYAG argues that "[i]n addressing the competent and reliable scientific evidence standard, Plaintiffs offered expert testimony showing that an RCT was in fact required to substantiate the challenged advertising claims." (Opp. at 14.) But the NYAG's experts had never even heard of the competent and reliable scientific evidence standard. (Trial Tr. at 304:6–12 (Dr. Sano admitting that, even though the FTC Advertising Guide does not require a specific type of study, she would require an RCT); 304:13–21 (Dr. Sano admitting that she did not know that the FTC Advertising Guide does not require a set protocol for research but that she would require a

very prescribed protocol); 309:21–24 (Dr. Sano admitting that she was not aware of the FTC Advertising Guide's statement that *in vitro* studies "will be examined"); 309:25—311:25 (Dr. Sano admitting that reputable journals in her field of memory and cognition have published research on animal models); 313:15–18 (Dr. Sano admitting that she was not aware of the FTC Advertising Guide's statement that animal studies "will be examined"); 494:10–14 (Dr. Wittes admitting that she "do[es]n't know anything about the relationship between the science and the advertising claims."); *see also* Trial Tr. at 497:2–6; 497:16–24; 299:20–22; 300:7–15; 483:21—484:7; 619:15–17; 622:3–6.)

Moreover, the jury plainly did not credit this testimony from the NYAG's experts that an RCT is required to substantiate the Challenged Claims because it found that six of the eight Challenged Claims were not materially misleading. Instead, the jury likely credited the Advertising Guide itself, as well as *Defendants'* experts, who testified that, consistent with the Advertising Guide, *all* forms of scientific evidence should be considered. (DX-526 at 10 (FTC Advertising Guide statement that "all forms of competent and reliable scientific research" will be considered, including "animal and in vitro studies"); Trial Tr. at 983:3—984:8 (Dr. Kurzer, an expert in nutritional science and dietary supplements, explaining why dog studies are particularly good models for human cognition); 1125:20—1126:11 (Dr. Schwartz, an expert in neuroscience and dietary supplement substantiation, explaining that animal and *in vitro* research are "all part of the portfolio of substantiation that's used to evaluate the science in relationship to the claims being made"); 1012:12—1014:10 (Dr. Kurzer explaining the importance of epidemiological studies in nutrition studies and why they are sometimes seen as stronger evidence than randomized controlled trials).)

The NYAG's Opposition attempts to distract from their experts' inability to evaluate the scientific evidence under the competent and reliable scientific evidence standard, by calling on Quincy to have provided documentary evidence in connection with the Madison Memory Study's data analysis. (Opp. at 16.) But the NYAG cannot shift the burden to Quincy to make up for the its own failures of proof. After years of discovery and ten days of trial, the NYAG still cannot point to any evidence to support their accusation that Quincy's "subgroup analyses were post hoc." (*Id.*) And as the Court noted, "it is a fair question to ask an expert the basis for his or her expert opinion or if his or her expert opinion assumes some fact which is unproved." (Dkt. 379, at 1–2.) That is exactly what happened here. The NYAG's experts concluded that the 0-1 and 0-2 subgroup analyses in question were "post hoc," but had no evidence to support those conclusions and, in fact, conceded that these conclusions were based on their own *assumptions* about how the Madison Memory Study was conducted and analyzed. (See Mot. at 13.) However, the uncontroverted evidence from Quincy's witnesses puts this issue to rest—there were no so-called "post hoc" data analyses, and Messers. Underwood, Olson, and Lerner testified that these subgroups were the intended study population and were among the first to be analyzed. (*Id.*) This makes perfect sense, given it was their intent to market a dietary supplement and not a drug. The NYAG cannot avoid this unrebutted testimony simply by characterizing it as "self-serving" (Opp. at 16), and certainly cannot rebut that testimony with the *assumptions* of their experts. *Shatkin*, 565 F. Supp. at 95 ("An expert's opinion that is founded in conjecture that is inconsistent with the record has no evidentiary value."); *see also Boots*, 132 F. Supp. 3d at 317 ("An expert's opinions that are without factual basis and are based on speculation or conjecture are simply inappropriate.") (internal citation omitted); *Macaluso*, 2005 WL 563169, at *8 ("An expert's opinion based on incorrect factual assumptions renders all of his subsequent conclusions purely speculative").

This is not a mere disagreement among experts, as the NYAG contends. The NYAG's proffered experts were completely in the dark. The NYAG allowed its experts to create their own standards—without *any* relevant context of the actual advertisements being challenged or *any* understanding of the applicable regulatory or legal framework—which consequentially held Quincy to an unknown, unpublished, heightened standard, violating Quincy's due process rights. In other words, the NYAG's experts provided answers to the wrong questions—they looked at whether the Madison Memory Study was a perfect study that would withstand drug approval scrutiny instead of evaluating whether the Madison Memory Study (and Defendants' other scientific substantiation) met the competent and reliable scientific evidence standard set forth in the Advertising Guide. (Mot. at 11–14.) This violates Due Process. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158–59 (2012); *NLRB v. Majestic Weaving, Co.*, 355 F.2d 854, 860 (2d Cir. 1966); *Stoller v. Commodity Futures Trading Comm'n*, 834 F.2d 262, 267 (2d Cir. 1987). Accordingly, Defendants are entitled to judgment as a matter of law on all counts.[2]

**C. Plaintiffs Failed To Rebut Dr. Kurzer.**

In addition to the other myriad failures of proof discussed in Quincy's motion, Defendants are entitled to judgment as a matter of law on all claims based on Dr. Kurzer's testimony that voluminous peer-reviewed research demonstrates a beneficial association between Vitamin D and

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[2] The NYAG also argues that Defendants "repeatedly claim in their advertising that Prevagen's efficacy was shown by an RCT." (Opp. at 17.) But the cited trial testimony relates only to the challenged "clinically shown" claims and the NYAG failed to offer any legal argument or factual evidence that a "clinically shown" claim is the equivalent of an "RCT." As the NYAG's own case law (again, from outside this Circuit) demonstrates, "clinically shown" is a non-specific establishment claim that does not reference any specific level of substantiation like an RCT. *See, e.g., FTC v. COORGA Nutraceuticals Corp.*, 201 F. Supp. 3d 1300, 1309 (D. Wyo. 2016) (holding that "scientifically proven" is a non-specific establishment claim that does not require a specific type of study, but rather must be supported by evidence that satisfies the scientific community).

cognitive function, and that those studies constitute competent and reliable scientific evidence in support of Challenged Claims. (Mot. at 14–15; Trial Tr. at 1011:25—1012:3; 1015:6–16.) The NYAG failed to rebut Dr. Kurzer's opinions, and argues now in Opposition "that the scientific evidence does not show that Vitamin D improves memory or cognition." (Opp. at 21.) But the NYAG's say-so is insufficient to rebut expert trial testimony to the contrary.

The NYAG first focuses on Dr. Sano's credentials, which, of course, are irrelevant to whether she adequately rebutted Dr. Kurzer's opinions. She did not. Dr. Sano testified that she did not believe there was evidence that Vitamin D improves memory or cognition "*in the general setting*." (Trial Tr. at 291:11–13 (emphasis added).) When pressed further, Dr. Sano admitted that she had "made a qualification . . . to talk about general public without talking about a Vitamin D deficient population." (*Id.* at 323:1–3.) But as Dr. Kurzer testified, nearly half of the American population is Vitamin D deficient. (*Id.* at 1007:11—1008:8.) Dr. Sano's opinion, by her own admission, does not apply to nearly half of the American population and does not rebut Dr. Kurzer's testimony at trial that voluminous peer-reviewed scientific evidence shows that "vitamin D appears to be protective and to improve cognitive function." (*Id.* at 1008:9–13.)

Second, despite the NYAG's contentions regarding the relevance of observational and epidemiological studies in proving causation, Dr. Kurzer's testimony at trial remains unrebutted. (Opp. at 19–20.) In fact, the NYAG's Opposition reiterates that Dr. Kurzer testified, unrebutted, that the studies she reviewed show a beneficial association between Vitamin D and improved cognition. (*Id.*) Dr. Sano did not even evaluate the studies that Dr. Kurzer reviewed, and certainly did not contradict Dr. Kurzer's testimony regarding this beneficial association. Dr. Sano merely testified that, in general, observational studies show an association, not causation. (Trial Tr. at 294:4–5.) Dr. Kurzer generally agreed with this statement, but nevertheless opined that the studies

constitute competent and reliable scientific evidence in support of the Challenged Claims. (*Id.* at 1007:7—1016:8.)

And while the NYAG points to this Court's ruling that Dr. Kurzer "may not draw an ultimate conclusion as to whether Prevagen impacts memory or cognition" (Opp. at 19), its Opposition ignores that this Court also ruled—no less than three times—that Dr. Kurzer's testimony is relevant to the substantiation of the Challenged Claims, both with respect to apoaequorin and Vitamin D. (*See* Dkt. 331, at 19 ("Dr. Kurzer is qualified to evaluate the quality of the defendants' scientific support for the challenged statements and whether the studies conducted by defendants to substantiate their marketing claims constitute competent and reliable scientific evidence."); Dkt. 379, at 2 ("Dr. Kurzer's testimony is relevant to issues in the case, including the quality of the scientific literature as support for the Prevagen claims, such as reports on the effect of Vitamin D."); Trial Tr. at 1008:9–24, 1009:2–15.)

The NYAG failed to provide any evidence to rebut Dr. Kurzer's testimony that 86 peer-reviewed studies on Vitamin D provide competent and reliable scientific evidence in support of the Challenged Claims as of the date that Vitamin D was added to Prevagen's formulation in 2016. Therefore, Defendants are entitled to a judgment as a matter of law on all of the Challenged Claims from 2016 forward.[3]

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[3] The NYAG notes that Prevagen is not marketed as a Vitamin D supplement. (Opp. at 21.) This is completely irrelevant. Since 2016, Prevagen has contained Vitamin D. If there is competent and reliable scientific evidence relating to Vitamin D that substantiates the Challenged Claims, none of those claims could be misleading or give rise to liability under New York law.

**D. Defendants Are Entitled To Judgment As A Matter Of Law On The Executive Law Claim.**

As set forth above and in their Motion, Defendants are entitled to judgment as a matter of law with respect to each of the Challenged Claims. But even if the Court disagrees with Defendants concerning the Jury Verdict Claims, Defendants are entitled to a judgment as a matter of law on the Executive Law claim with respect to (at a minimum) the six Challenged Claims that the jury found were not materially misleading and did not violate the GBL. This is because—as the Court has already held—no independent cause of action exists under New York Executive Law. This is law of the case and cannot be relitigated by the NYAG, no matter how many times it tries. *See Johnson v. Holder*, 564 F.3d 95, 99 (2d Cir. 2009) ("The law of the case doctrine commands that when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case.")

The NYAG's statement that the jury's finding that six of the eight Challenged Claims "has no bearing" on the Executive Law claim is without merit. (Opp. at 26.) As discussed above, the jury found the NYAG did not carry its burden of proof on its GBL cause of action for six of the eight Challenged Claims. Because the Executive Law claims "rises and falls" with the GBL claims, the jury's determination that the claims were not materially misleading dooms the Executive Law claim. *People v. One Source Networking, Inc.*, 125 A.D.3d 1354, 1355–56 (4th Dep't 2015); *Frink Am. Inc.*, 2 A.D.3d at 1380; *City of New York v. FedEx Ground Package Sys., Inc.*, 175 F. Supp. 3d 351, 363-64 (S.D.N.Y. 2016); *Consumer Fin. Prot. Bureau v. RD Legal Funding, LLC*, 332 F. Supp. 3d 729,784 (S.D.N.Y. 2008); *People v. Exxon Mobil Corp.*, 65 Misc.3d 1233(A), at *4 (Sup. Ct. N.Y. Cnty. 2019); *People v. Mashinsky*, 79 Misc.3d 1237(A), at *16 (Sup. Ct. N.Y. Cnty. 2023) (Martin Act and Executive Law claim "stand and fall together");

*State v. MedImmune, Inc.*, 342 F. Supp. 3d 544, 557 (S.D.N.Y. 2018) (recognizing Executive Law § 63(12) does not create a new cause of action).

In its Opposition, the NYAG rehashes its already rejected argument that an independent cause of action exists by citing *Matter of People v. Trump Entrepreneur Initiative LLC*, 137 A.D. 3d 409 (1st Dep't 2016). But, the *Trump Entrepreneur* case is at odds with both the weight of authority cited by Defendants (and the New York Court of Appeals' *Cortelle* decision) and what this Court already found to be the correct interpretation of Executive Law[4] and so instructed the jury. (*See* Trial Tr. at 1447:21—1448:8) ("If you do not find the Quincy defendants libel [*sic*] under the general business law sections, then you do not need to reach the Attorney General's charge under the New York Executive Law because, in effect, that charge has already been disposed of" because there is no independent cause of action under the Executive Law); *One Source Networking, Inc.* 125 A.D.3d at 1355–56 ("Respondents are correct that section 63(12) does not create an independent cause of action . . . Rather, that section is only a mechanism by which a petitioner may show that injunctive relief and restitution are proper in the event that the petitioner establishes that a respondent violated *other statutes*" (emphasis added)).

As courts in *this* district have also held—including earlier *this year*—"[S]ection 63(12) 'creates[s] no new claims but ... provide[s] particular remedies and standing in a public officer to seek redress on behalf of the State and others.'" *FedEx Ground Package Sys.*, 175 F. Supp. 3d at

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[4] In *Trump Entrepreneur*, the NYAG commenced a special proceeding under Executive Law 63(12) in New York state court. 137 A.D.3d at 411. The Executive law provides that the NYAG "may apply . . . to the supreme court of the state of New York, on notice of five days, for an order enjoining the continuance of such business activity or of any fraudulent or illegal act. . . ." N.Y. Exec. Law § 63(12). Here, the NYAG did not commence a special proceeding in the state supreme court nor provide the requisite five days' notice. Accordingly, this provides an additional basis to grant Defendants judgment as a matter of law on the NYAG's Executive Law claim.

364 (S.D.N.Y. 2016) (citing *People v. Frink Am. Inc.*, 770 N.Y.S.2d 225, 226 (4th Dep't 2003) (quoting *State v. Cortelle Corp.*, 38 N.Y. 2d 83, 86 (N.Y. 1975)); *MedImmune, Inc.*, 342 F. Supp. 3d at 557 ("New York's claims under Executive Laws §§ 63(12) and 63-c . . . do not 'create a new cause of action, but rather give[] an additional remedy upon which the State can recover.'"); *New York v. Arm or Ally, LLC*, ---F. Supp. 3d---, No. 1:22-cv-06124, 2024 WL 756474, at * 3 (S.D.N.Y. Feb. 23, 2024) (acknowledging Executive Law § 63(12) claims are based on allegations that "Defendants' business practices violated various local, state, and federal laws and, *on that basis*" sought relief under the Executive Law.)

The cases cited in the NYAG's opposition, (Opp. at 24), do not support its position that there is a standalone cause of action under the Executive Law. They fall into three categories, none of which are applicable here: some of the NYAG's cases stand for the uncontroversial and inapposite proposition that a 63(12) claim was adequately *pled* at the pleading stage, along with the other primary causes of action, which has no bearing on the applicable burden of proof for a 63(12) claim. *See People v. Debt Resolve, Inc.*, 387 F. Supp. 3d 358, 365 (S.D.N.Y. 2019); *RD Legal Funding, Inc.*, 332 F. Supp. 3d at 767. Others simply follow the *Trump Entrepreneur* decision without analyses. *See People v. Wu*, No. 452904/2022, 2024 WL 776820, at *13 (N.Y. Sup. Ct. Feb. 26, 2024). Still, others involved a special proceeding upon the required five days' notice unlike what the NYAG pursued here. *See People v. Sec. Elite Grp.*, No. 450025/2015, 2015 WL 9271698 at *5 (Dec. 18, 2015)

Indeed, several of the NYAG's cited cases support *Defendants'* position as reflected in the Court's jury instruction that there is no independent cause of action under the Executive Law. *See RD Legal Funding, Inc.*, 332 F. Supp. 3d at 784 ("because the elements of a claim under Section 63(12) are *entirely encompassed* by the elements of deceptive conduct under the CFPA or NY

GOL § 349 that the Government has already adequately pled, the Complaint contains sufficient allegations to state a claim under N.Y. Executive Law § 63(12) as well"); *Exxon Mobil Corp.*, 65 Misc.3d 1233(A), at *4 ("acts that violate the Martin Act also violate Executive law § 63(12)").

As the abundance of case law *other* than the outlier *Trump Entrepreneur* case and its progeny from one department (that is at odds with Court of Appeals' precedent and the plain text of the Executive Law) clearly states, there is no standalone cause of action for fraud under the Executive Law. *See, e.g.*, (Mot. at 16–17); *One Source Networking, Inc.*, 125 A.D.3d at 1355–56; *Frink Am. Inc.*, 2 A.D.3d at 1380; *FedEx Ground Package Sys.*, 175 F. Supp. 3d at 363–64; *RD Legal Funding, Inc.*, 332 F. Supp. 3d at 784; *Exxon Mobile Corp.*, 65 Misc.3d 1233(A), at *4; *Mashinsky*, 79 Misc.3d 1237(A), at *16 (Martin Act and Executive Law claim "stand and fall together"); *MedImmune*, 342 F. Supp. 3d at 557 (recognizing Executive Law § 63(12) does not create a new cause of action); *Arm or Ally, LLC*, 2024 WL 756474, at *3.

The NYAG further argues—based solely on the *Trump Entrepreneur case*— that a 63(12) claim does not require a finding of materiality. But this decision is at odds with the Court's instruction to the jury as discussed above (*see* Trial Tr. at 1447:21—1448:2), as well as other cases cited in the NYAG's own brief. For example, in *People v. Exxon Mobil Corp*, the New York Supreme Court, New York County (the same court that issued the *Trump Entrepreneur* decision) conducted a bench trial on claims asserted under the Martin Act and under Executive Law 63(12). *See Exxon Mobil Corp.*, 65 Misc.3d 1233(A) at *1. The court engaged in a lengthy analysis of the "materiality" and "misleading" elements under the Martin Act, and then dismissed both the Martin Act claims *and* the Executive Law claims without any further analysis of liability under the Executive Law. *See id.* at *3. This case undermines the NYAG's position that its Executive Law claim can survive in light of the jury's findings on the GBL claim for the six of the eight Challenged

Claims found not to be materially misleading. Moreover, in *People v. GE*, which is cited by *People v. Trump* for the materiality point raised by the NYAG, the court specifically found that the challenged conduct was both "misleading in a material way" under the GBL *and* had the capacity or tendency to deceive" under Executive Law 63(12). *See People v. GE,* 302 A.D.2d 314, 314–15 (1st Dep't 2003). Thus, the *GE* decision also fails to support the NYAG's position here that liability under the Executive Law can be imposed absent liability under the GBL.

Accordingly, Defendants are entitled to judgment as a matter of law in their favor on the NYAG's Executive Law claim.

## III. CONCLUSION

For the foregoing reasons and those set forth in their moving brief, Defendants respectfully request that this Court grant Defendants' renewed motion for judgment as a matter of law and grant judgment in favor of Defendants on all counts.

Date: April 29, 2024

KELLEY DRYE & WARREN LLP

By: */s/ Geoffrey W. Castello*

John E. Villafranco (*pro hac vice*)
Geoffrey W. Castello
William A. Escobar
Jaclyn M. Metzinger
Glenn T. Graham
Caitlin R. Hickey
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 808-7800
Fax: (212) 808-7897
jvillafranco@kelleydrye.com
gcastello@kelleydrye.com
wescobar@kelleydrye.com
jmetzinger@kelleydrye.com
ggraham@kelleydrye.com
chickey@kelleydrye.com

*Counsel for Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC*

COZEN O'CONNOR, P.C.

By: */s/ Michael de Leeuw*

Michael de Leeuw
Tamar S. Wise
Amanda Giglio
Robert Clark
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 908-1331
mdeleeuw@cozen.com
twise@cozen.com
agiglio@cozen.com
rclark@cozen.com

*Counsel for Defendant Mark Underwood*